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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE DEC 11 2003

In re Application of: Allen Comer *et al.*

Serial No.: 10/087,388

Filed: 03/01/02

Entitled: Skin Substitutes for Irritancy Testing

Group No.: 1634

Examiner: Switzer

RESPONSE TO RESTRICTION REQUIREMENT  
MAILED JUNE 6, 2003Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.2(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: 9/5/03

By: *Mary Ellen Wain*

Dear Sir or Madam:

This communication is responsive to the Restriction Requirement mailed June 6, 2003, in the above-mentioned application. The Restriction Requirement set a shortened statutory period of one month for Applicants' response. Accompanying this communication is a Request for a two-month extension of time for responding to the outstanding Restriction Requirement. Applicants hereby authorize the Commissioner of the Patent and Trademark Office to charge Attorney Deposit Account No. 08-1290 the fee associate with this extension and any other fees associated with this communication. Please reference Attorney Docket No.: STRATA-06948 when charging the Attorney Deposit Account.

The amendments presented below are in compliance with the revised amendment format permitted in the Notice from the Office of Patent Legal Administration of the U.S. Patent and Trademark Office dated February 10, 2003, and published at 1267 OG 106 on February 25, 2003. Thus, the provisions of 37 CFR 1.121(a), (b), (c) and (d) are waived for amendments made in this application to the claims. *Amendments to the Claims* begin on page 2 of this paper. *Listing of the Claims* begins on page 3 of this paper. *Remarks* begin on page 5 of this paper.

**Amendments to the Claims:**

Please cancel claims 10 - 24.

**Listing of the Claims**

1. (Original) A method of screening compounds suspected of being skin irritants, comprising:
  - a) providing
    - i) a compound suspected of being a skin irritant;
    - ii) a skin equivalent comprising a irritant responsive reporter gene construct; and
  - b) contacting said skin equivalent with said compound; and
  - c) measuring the level of gene expression from said reporter gene construct.
2. (Original) The method of Claim 1, wherein said human skin equivalent has a surface electrical capacitance of from about 80 to about 120 pF.
3. (Original) The method of Claim 1, wherein the content of ceramides 5, 6, and 7 in said skin equivalent is from about 20 to about 50% of total ceramide content.
4. (Original) The method of Claim 1, wherein the content of ceramide 2 in said skin equivalent is from about 10 to about 40% of total ceramide content.
5. (Original) The method of Claim 1, wherein said skin equivalent comprises keratinocytes selected from the group consisting of primary keratinocytes and immortalized keratinocytes.
6. (Original) The method of Claim 5, wherein said immortalized keratinocytes are NIKS cells.
7. (Original) The method of Claim 1, wherein said keratinocytes express heterologous Kruppel-like factor 4.

8. (Original) The method of Claim 1, wherein said irritant responsive reporter construct comprises at least a portion of a gene selected from the group consisting of interleukin-8 and interleukin-1 $\alpha$ .

9. (Original) The method of Claim 1, wherein said portion comprises a regulatory region.

10 - 24. (Canceled)

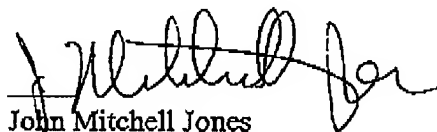
**REMARKS**

Claims 1-24 were originally filed in the present application. In the Restriction Requirement mailed June 6, 2003 the Examiner restricted claims 1-24 into three groups.

Applicants herein elect, without traverse, to prosecute the claims of Group I (claims 1-9). Applicants also herein cancel claims 10 - 24 in order to further their business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and while preserving the right to prosecute the canceled (or similar) claims in the future.

Claims 1 - 9 are pending and under examination following entry of Applicants' response to the outstanding Restriction Requirement.

Dated: 9/5/03



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